DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

Device Name

EsoFLIP® ES catheter

Indications for Use *(Describe)*

The EsoFLIP® ES balloon catheter is indicated for use to dilate esophageal strictures due to esophageal surgery, primary gastro-esophageal reflux, radiation therapy.

Note: The EsoFLIP® ES catheter is to be used only with the EndoFLIP® system.

Type of Use *(Select one or both, as applicable)*

XX Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*